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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/471,276	12/21/1999	Jean-Baptiste Dumas Milne Edwards	GENSET.025CP1	7217

7590 01/14/2003

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EXAMINER

ZHOU, SHUBO

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 01/14/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/471,276

Applicant(s)

EDWARDS ET AL.

Examiner

Shubo "Joe" Zhou

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 April 2002 and 04 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1,4-8,10-13,17 and 19-24 is/are pending in the application.
- 4a) Of the above claim(s) 1,4-8,10-13,17,19-21 and 24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22 and 23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 July 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☒ The proposed drawing correction filed on 04 November 2002 is: a) ☒ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Applicant's amendment and request for reconsideration in Paper #12, filed on 4/19/02, is acknowledged and the amendments entered.

The amendment to Fig. 1 proposed by applicants in Paper 16, filed on 11/4/02 is approved by the Examiner. The formal drawing filed 7/31/02 are not accepted by the Draftsman.

The substitute specification filed on 4/19/02 is received and entered.

Claims 1, 4-8, 10-13, 17, 19-24 are currently pending, but only claims 22-23 are under consideration.

Applicants argue that the newly added claim 24 belongs to Group II for it is the Office's policy. This is not found persuasive because claim 24 clearly is directed to a process of making the polypeptide of claim 22. As set forth in the previous Office action mailed 9/25/01, the inventions can be shown to be distinct if either or both of the following can be shown: (1) the process as claimed can be used to make other and materially different product or (2) the product as claimed can be made by another and materially different process (MPEP §806.05(f)). In the instant case, the polypeptides of claim 22 can be produced by the process of invention of Group IV, and the invention of claim 24. Alternatively, the polypeptides can be produced by chemical synthesis, clearly a materially different process. Thus, claim 24 and the invention of Group II (claim 22-23) are distinct.

Applicant's arguments in response to the previous Office Action, have been fully considered but they are not deemed to be persuasive. The following rejections and/or objections are either reiterated from the previous Office action(s) or newly added, and constitute the

complete set presently being applied to the instant application. Rejections and/or objections not reiterated from previous Office action are hereby withdrawn.

Claim Rejections-35 USC § 101 and § 112

Claims 22-23 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific asserted utility or a well established utility. This rejection is reiterated from previous Office action and maintained for reasons of record.

Applicants' argument is on the ground that the polypeptide as claimed comprises a signal peptide and thus has specific and substantial utility. This is not deemed persuasive because there are multiple distinct polypeptides comprising different signal peptides with distinct utilities. The mere fact that a polypeptide comprises a signal peptide does not automatically render to it a specific and substantial utility. It takes further research to determine what, if any, real world utility the claimed polypeptide comprising the signal peptide possesses.

Claims 22-23 are also rejected under 35 U.S.C. 112, first paragraph.

Specifically, since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. This rejection is reiterated from previous Office action and maintained because applicants' argument against the rejection of the claims under 35 U.S.C. 101 is not deemed persuasive as set forth above.

Claim Rejections-35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobs et al. (Database Geneseq accession #AAV88297, 12 Feb. 1999, and WO 98/45437, 15 October, 1998) in view of Watson et al. (Recombinant DNA, second edition, Scientific American Books, 1994).

Claim 22 is drawn to a polypeptide comprising the amino acid sequence of -16 to -1 of SEQ ID NO:831.

Jacobs et al. disclose a cDNA sequence encoding a polypeptide comprising the amino acid sequence of -16 to -1 of the instant SEQ ID NO:831. See the attached sequence alignment between the sequence of Geneseq acc. # AAV88297 and -16 to -1 of SEQ ID NO:831. Note that the sequence of Geneseq acc. # AAV88297 is from WO 98/45437 as disclosed in the text portion of the attached sequence alignment.

Geneseq acc. # AAV88297 also disclose that the sequence encodes a secreted protein and has utility in haematopoiesis regulation, etc. This would have motivated an ordinary skill in the art to make the polypeptide encoded by the polynucleotide in order to further study the polypeptide. Watson et al. disclose a detailed procedure of cloning and expressing a polypeptide in bacterial cells. See pages 63-77. Thus, the claimed invention would have been obvious to an ordinary skill in the art at the time the invention was filed. There would have been a reasonable expectation of success because Jacobs et al. provided the DNA sequence and Watson et al. provided the procedure of producing the polypeptide encoded by the DNA.

Conclusion

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to:

Shubo "Joe" Zhou, Ph.D., whose telephone number is (703) 605-1158. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Technical Center receptionist whose telephone number is (703) 308-0196.

S. "Joe" Zhou, Ph.D.



Patent Examiner



MICHAEL P. WOODWARD
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600